**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>L'ORÉAL USA, INC.,<br><br>Defendant. | C.A. No. 17-cv-868-CFC-SRF |

**PLAINTIFFS' RESPONSIVE CONCISE STATEMENT OF FACTS IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF NO ANTICIPATION**

DATED: October 16, 2020

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***Attorneys for Carmel Laboratories, LLC***

| Plaintiffs' Responses to Defendant's Allegedly Undisputed Facts[1] | | |
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| | **Allegedly Undisputed Facts** | **Plaintiffs' Response** |
| 40 | Plaintiffs distinguished DE107 during prosecution, at the PTAB to avoid *inter partes* review, and at *Markman* on the basis that the claims of the patents-in-suit require no increase in dermal cell proliferation, but now agree that DE107 likewise does not disclose an increase in dermal cell proliferation. (D.I. 285, ¶¶ 8-16.) | Undisputed that the named inventors and Patent Owner (not "Plaintiffs") distinguished DE107 during prosecution and before the PTAB, and Plaintiffs distinguished DE107 during *Markman*, citing the inventors' declaration referencing dermal proliferation. D.I. 311, ¶¶ 9, 12, 15-16. Disputed that "Plaintiffs agree DE107 likewise does not disclose an increase in dermal cell proliferation." D.I. 310, at 12 n. 2; 311, ¶¶ 21-25. |
| 41 | The patents-in-suit do not exemplify any specific formulations and their claims do not recite formulation features at all (*e.g.*, limitations for a specific "preservative," "fragrance," "carboxyvinyl polymer," or "manufacturing method"). (Ex. A, claims 1, 3; Ex. B, claims 1, 3.) | Undisputed that the patents-in-suit do not provide ingredient lists for specific formulations, or include limitations for a specific preservative, fragrance, carboxyvinyl polymer, or manufacturing method. L'Oréal's inferences are disputed. |

[1] The Court's rule appears to be that concise statements of fact may only be 1750 words total, but L'Oréal's three opposition statements of fact total 3750 words (fewer than 1750 each). In order to respond, Plaintiffs have had to exceed a total of 1750 words, but have made every effort to keep their responses as concise as possible.

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| 42 | Plaintiffs accuse L'Oréal USA products of infringement with the same adenosine concentrations (0.1%) as many example formulations disclosed in the prior art, which also discloses adenosine concentrations of, *inter alia*, 100 times more (10%) and 100 times less (0.001%) being topically applied to enhance the condition of the skin. (Ex. GG at 1:3-2:10, 2:28-3:5, 14:17-20, Examples 1-6, claims; Ex. II at 5:7-16, 9:18-10:8, 10:12-19:15; Ex. KK at 378-79 & tbl; Ex. HH at 1-3, Example 2, claims; Ex. DD at Abstract, 1:8-23, 2:9-26, 3:27-39, 8:23-35, Examples 4, 10; Ex. EE at 1:41-44, Examples 1-3; Ex. C, ¶¶ 45, 48-50, 64-68.) | Undisputed that L'Oréal represents that some of the accused products contain 0.1% wt adenosine. Undisputed that certain prior art references disclose adenosine concentrations of 0.001%-10%. L'Oréal's inferences are disputed. |
| 43 | The broad adenosine concentration ranges in the prior art disclose adenosine reaching the dermis at the claimed concentrations. (Ex. C, ¶¶ 88-89, 94, 108-109, 113, 126-128, 132, 142-144, 148, 160-162, 166, 178-180, 184; D.I. 285, ¶¶ 24-30.) | Disputed. D.I. 311, ¶¶ 24-30. |
| 44 | L'Oréal USA's expert Dr. Gerald Kasting explained how the patents-in-suit correlate the concentrations of adenosine to effects on the skin as a whole, and how the prior art discloses the same improvements in skin condition through use of adenosine. (Ex. C, ¶¶ 88 (citing Ex. A at 1:37-41, 5:44-48), 108,126, 142, 160, 178.) | Undisputed that Kasting's report says "the patents-in-suit purport to correlate the concentrations of adenosine applied directly to skin fibroblasts in culture with *in vivo* effects on the skin as a whole." Ex. C, ¶ 88.[2] L'Oréal's inferences are disputed. D.I. 311, ¶¶ 24-30. |

[2] Citations to "Ex. __" are to L'Oréal's exhibits. Citations to "Appx__" are to Plaintiffs' appendices.

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| 45 | Kasting supports his anticipation opinions with named inventor Dr. James Dobson's testimony that, "if a composition of adenosine is applied to the skin and it enhances the condition of the skin, it must reach the dermal cell layer in the concentrations claimed in [his] patents, the '327 and '513 patents." (Ex. O at 212:5-13, 135:4-10, 139:4-12; Ex. C, ¶¶ 88, 108, 126, 142, 160, 178.) | Undisputed that the cited paragraphs of Kasting's report quote Dobson's testimony Undisputed that Dobson testified he prepared adenosine compositions, applied them to himself, and observed resulting skin enhancement. Ex. O, at 134:14-23. Undisputed that when asked, "Based on that assessment, you understood that adenosine in the concentrations that are claimed in the patent had reached the dermal layer?" Dobson responded, "Yes, I did assume that." And when asked, "That's because if you're showing efficacy after the application of a composition containing adenosine, it would mean that adenosine is getting to the dermal layer at an amount effective to result in the enhancement of the condition of the skin; is that correct?" he answered "That's a logical assumption." *Id.* at 137:20-138:7. Undisputed that when L'Oréal's counsel subsequently used the language L'Oreal quotes, Dr. Dobson responded, "You got it." *Id.* at 212:5-11. |
| 46 | According to Dobson, the claims do not require identifying a specific number or exact value for the concentration of adenosine that reaches the dermis to meet the claimed ranges. (Ex. O at 212:5-13, 135:4-10, 139:4-12.) | Disputed. This summary mischaracterizes Dobson's testimony. Ex. O, at 135:4-10, 139:4-12, 212:5-13. |

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| 47 | Kasting identified adenosine as the "most active agent in the composition" with respect to the '164 patent (Ex. R at 207:1-211:13), and Plaintiffs do not argue that any of the anticipatory references besides the '164 patent use "both adenosine and hyaluronic acid." (D.I. 260 at 6.) | Disputed. Kasting testified that "it could have been one or both of" adenosine or hyaluronic acid "or, for that matter, other ingredients in there" enhancing the condition of the skin. Ex. R at 207:7-18. |
| 48 | When asked about specific prior-art references, Kasting was clear on which ones disclose compositions that anticipate the claimed range and why. (Ex. R at 158:22-162:2; 182:16-184:19; 190:15-204:17, 179:6-180:17.) | Disputed. D.I. 260, at 3-10; 310, at 7-11. |
| 49 | Kasting supports his anticipation opinions with evidence from the '089 patent and JP915 that the claimed dermal concentrations of adenosine analogs were known to enhance skin condition. (Ex. R at 163:9-165:4, 168:9- 169:1, 186:12-188:15, 194:11-195:23; Ex. C, ¶¶ 55-58, 69, 215; Ex. E, ¶¶ 20-21, 33, 72-73, 76, 78-81; Ex. FF at Abstract, 7:35-37, 8:40-45; 23:5-33; 25:67-26:3; Ex. JJ at ¶¶ 2, 4-5, 20-31.) | Undisputed that Kasting's report cites the '089 and JP915 patents. L'Oréal's inferences are disputed. AppxG000007, 10; Ex. I, ¶¶ 146-49. |

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| 50 | L'Oréal USA's expert Dr. Majella Lane made and tested two formulations disclosed in the prior art (DE107 Example 5 and JP153 Comparative Example 1), and showed how those prior art formulations resulted in adenosine concentrations being achieved at the dermis within the claimed ranges. (Ex. F, ¶¶ 19-22, 34, 36.) | Undisputed that Lane's report says she conducted testing of two formulations and opined that "if Plaintiffs contend that such Franz diffusion cell testing is an appropriate methodology for determining [transdermal permeation] the experiments . . . show that applying topically the DE107 and JP153 formulations causes adenosine to penetrate through the epidermal layer to apply to the dermal cell layer in those claimed numerical concentration ranges." Ex. F, ¶ 36. L'Oréal's inferences are disputed. |
| 51 | Lane testified that her tested formulations were "representative" of DE107 Example 5 and JP153 Comparative Example 1. (Ex. S at 345:15-346:23, 349:16-350:6; Ex. G, ¶¶ 7-10, 12-14.) | Undisputed that Lane testified "I think that the formulations I made are representative of what's in Table 5 in DE107 and what's in Comparative Example 1 of JP153" and her report states that she has not seen any evidence her compositions "were not representative." Ex. S, at 346:15-17; Ex. G, ¶¶ 10, 14. Lane could not identify the basis for this opinion in her report, Ex. S, at 349:23-350:6, and L'Oréal's inferences are disputed. |

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| 52 | For Lane's DE107 formulation, "[t]he mean value for the adenosine concentration in the dermis for all six cells [to which the formulation was applied] [was] 2.62 x 10-6 M" and, for her JP153 formulation, "[t]he mean value for the adenosine concentration in the dermis for all six cells [to which the formulation was applied] [was] 1.09 x 10-5 M," both of which fall within the broad ranges recited in claims 1 and 3 of the patents-in-suit. (Ex. F, ¶ 34.) | Undisputed that Lane reports the results of her testing as providing the identified mean values. L'Oréal's inferences are disputed. |
| 53 | Lane's JP153 formulation always produced test results within the claimed ranges. (Ex. F, ¶ 34; Ex. A, claims 1, 3; Ex. B, claims 1, 3.) | Undisputed that Lane reported results for her JP153 formulation testing that fall within the range $10^{-3}$ M to $10^{-7}$ M. |
| 54 | Dr. Bozena Michniak-Kohn's opinion that changes to adenosine penetration due to variations in unclaimed manufacturing methods, ingredients, or amounts of ingredients could make a difference with respect to meeting the broad ranges recited in the claims was unsupported by specific evidence, and her opinion was not left unrebutted. (Ex. E, ¶¶ 46-47, 51-52; Ex. G, ¶¶ 8-10, 13-14.) | Disputed. AppxA000246-252. |
| 55 | Plaintiffs do not dispute that the formulation "choices Lane made were well accepted." (D.I. 260 at 12; Ex. G, ¶¶ 6-14.) | Undisputed to the extent Lane chose ingredients and manufacturing methods that were known to a POSITA in the 1997-1998 time period. Disputed to the extent L'Oréal implies Lane's discretionary choices were disclosed or condoned by the prior art. AppxA000246-252. |

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| 56 | To the extent Plaintiffs argue Lane's particular *in vitro* test methodology is flawed, Lane disagrees. (Ex. G, ¶¶ 15-21.) | Undisputed that Lane disagrees with Plaintiffs' criticisms of her testing methodology. |
| 57 | The patents-in-suit do not specify how to determine whether the claimed concentrations have been met by topical application of a composition. (Ex. A; Ex. B.) | Disputed. Ex. I, ¶¶ 169-180, 213-230. |
| 58 | The patents-in-suit do not demonstrate criticality of the ranges recited in claims 1 or 3 of either patent. (Ex. A; Ex. B.) | Disputed. The patents-in-suit say that the "therapeutically effective amount of adenosine" applied to the dermal cells is "preferably $10^{-3}$ to $10^{-7}$ M, more preferably $10^{-3}$ [or $10^{-4}$] to$10^{-6}$ M." Ex. A, at 2:13-16. |

DATED: October 16, 2020

Respectfully submitted,

FARNAN LLP

*/s/ Brian E. Farnan*

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# APPENDIX IN SUPPORT

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>L'ORÉAL USA, INC.,<br><br>Defendant. | C.A. No. 17-cv-868-CFC-SRF |

**DECLARATION OF BEATRICE FRANKLIN**

I, Beatrice Franklin, declare as follows:

I am an attorney at the law firm Susman Godfrey, L.L.P. and am counsel of record for Plaintiffs University of Massachusetts and Carmel Laboratories, LLC ("Plaintiffs") in the above-captioned matter. I hereby submit this declaration in support of Plaintiffs' Motion for Partial Summary Judgment of No Anticipation.

1. Attached as Exhibit 1 is a true and correct copy of L'Oréal USA's Notice of Deposition of Plaintiffs Pursuant to Rule 30(b)(6).

2. Attached as Exhibit 2 is a true and correct copy of an email exchange between counsel in this matter, dated May 16-26, 2020.

3. Attached as Exhibit 3 is a true and correct copy of the October 16, 2020 Declaration of Dr. Ryan Cheu.

4. Attached as Exhibit 4 is a true and correct copy of the October 16, 2020 Declaration of Dr. Bozena Michniak-Kohn.

Dated: October 16, 2020

*/s/ Beatrice Franklin*
Beatrice Franklin

# EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>L'ORÉAL USA, INC.,<br><br>Defendant. | ) | C.A. No. 17-868-CFC-SRF |

**L'ORÉAL USA'S NOTICE OF DEPOSITION OF PLAINTIFFS PURSUANT TO RULE 30(b)(6)**

**PLEASE TAKE NOTICE** that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure and the Orders of this Court, on a date and at a location to be agreed upon by the parties, and continuing day to day until completion, or resuming until completion on a date set by Defendant L'Oréal USA, Inc. ("L'Oréal USA" or "Defendant"), by further notice or by mutual agreement of the parties, attorneys for L'Oréal USA will take the following videotaped deposition(s) upon oral examination, under oath, before a qualified notary public or certified court reporter of Plaintiffs University of Massachusetts Medical School ("UMass") and Carmel Laboratories, LLC ("Carmel Labs") (together, "Plaintiffs") on the topics set forth in Schedule A. Plaintiffs shall identify the individual(s) they designate to testify on their behalf in response to the topics and the topics on which each such individual will provide testimony not less than ten (10) business days in advance of the commencement of the deposition(s). Plaintiffs must designate persons with sufficient knowledge and preparation to testify on all information known or reasonably available to Plaintiffs on these topics. Defendant reserves the right to notice and

take further depositions of Plaintiffs as necessary on additional topics in accordance with Rule 30(b)(6).

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Dated: April 8, 2020

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**SCHEDULE A**

**DEFINITIONS**

1. As used herein, the term "'327 patent" means United States Patent No. 6,423,327.

2. As used herein, the term "'513 patent" means United States Patent No. 6,645,513.

3. As used herein, the terms "Asserted Patents" and "Patents-in-Suit" mean, collectively, the '327 patent and the '513 patent.

4. As used herein, the term "PTO" means the United States Patent and Trademark Office.

5. As used herein, the term "Related Patents and Applications" shall mean any and all patents and patent applications that claim priority, directly or indirectly, to the Patents-in-Suit or to which at least the Patents-in-Suit claim priority, directly or indirectly (including any continuations, continuations-in-part, divisionals, provisional applications, reexaminations, or reissue patents or patent applications), whether domestic or foreign.

6. As used herein, the term "Document" is defined broadly to be given the full scope of that term contemplated in Rule 34 of the Federal Rules of Civil Procedure, including but not limited to correspondence, memoranda, transcripts of any conversation or testimony, recordings, stenographic or handwritten notes, studies, publications, books, pamphlets, pictures (drawings and photographs), films, microfilms, voice recordings, reports, recommendations, faxes, listings of telephone calls, emails, diaries, text messages, social media content, and computer programs and files or other electronically stored information (translated into a reasonably usable form, if necessary, by any Person or entity that has control of such records), and includes all tangible things, all originals (or, if originals are not available, identical copies thereof), all non-identical copies of a document, all drafts of final documents, all other written, printed, or recorded matter of any kind, and all other data compilations from which information can be obtained and

translated if necessary, that are or have been in your actual or constructive possession or control, regardless of the medium on which they are produced, reproduced, or stored, and, without limitation, all things meeting the definitions of "writings" and "recordings" as set forth in Fed. R. Evid. 1001.

7. As used herein, the term "Things" means any physical or tangible item, including samples, prototypes, and packaging.

8. As used herein, the term "Concerning" means in any way, directly or indirectly, regarding, considering, constituting, comprising, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, or having any connection with the matter discussed.

9. As used herein, the term "Communication" refers to all conversations, agreements, inquiries, or replies, whether in person, by telephone, in writing, or by means of electronic transmittal devices, and includes, but is not limited to, all correspondence, emails, recordings, transmittal slips, memoranda, telephone communications, voice messages, or notes.

10. As used herein, the terms "You," "Your," "UMass," "Carmel Labs," or "Plaintiffs" mean University of Massachusetts and/or Carmel Laboratories, LLC, and their respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors, and successors, including any entities or Persons acting on behalf of the University of Massachusetts and/or Carmel Laboratories, LLC and the named inventors of the Patents-in-Suit and/or Related Patents and Applications.

11. As used herein, the term "Person" means any natural person or business, legal, or governmental entity or association.

12. As used herein, the term "product" or "products" refers to any product, device, apparatus, process, method, system, media, or instrumentality.

13. As used herein, the term "Easeamine Product(s)" refers to any product (whether conceived, under development, developed, marketed, offered for sale, sold, or the like) identified in paragraphs 14-17 of the First Amended Complaint (D.I. 13), including the "anti-aging face cream" identified as "Easeamine," as well as any previous or later generations or versions, and derivations of those products, including any derivation currently under consideration and/or development.

14. As used herein, the term "Accused Products" refers to any product that You accuse L'Oréal USA of infringing any claim of any of the Patents-in-Suit.

15. As used herein, the term "Customer" means any Persons, including distributors and salons, to whom You have offered to sell or have sold any of Your Easeamine Products.

16. Any Person Concerning a corporation or business entity, and any reference to a corporation or business entity, includes all entities and Persons acting on the entity's behalf as well as all affiliates, divisions, parents, subsidiaries, predecessors, and successors thereof.

17. The terms "and" and "or" shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest request for disclosure of information is achieved.

18. The term "all" means all and each and the term "each" means each and all so that the fullest request for disclosure of information is achieved.

19. The singular includes the plural and the plural includes the singular so that the fullest request for disclosure of information is achieved.

## INSTRUCTIONS

1. All terms not otherwise defined herein shall have their ordinary meanings.

2. The plural form of words shall also mean and include the singular form of the same. Similarly, the singular form of words shall also mean and include the plural form of the same.

3. The terms "or" and "and" shall be construed conjunctively or disjunctively whenever necessary to bring within the scope of the topics identified below any information that might otherwise be construed as outside of their scope.

4. The terms "any," "all," "each," and "every" mean "each and every."

5. All verbs used herein shall be construed to include all tenses.

**TOPICS**

1. The distribution of Easeamine Products, including Your Communications with distributors and potential distributors of Easeamine Products, regarding all distribution of Easeamine Products.

2. Your Communications and agreements with beauty insiders, beauty influencers, skincare professionals, distributors, journalists, reporters, bloggers, marketing professionals in the beauty industry (including skincare), and social media influencers regarding the Accused Products.

3. Your Communications and agreements with beauty insiders, beauty influencers, skincare professionals, distributors, journalists, reporters, bloggers, marketing professionals in the beauty industry (including skincare), and social media influencers regarding Easeamine Products.

4. Monthly sales of Easeamine Products since inception, by distributor and SKU, on a unit and revenue basis.

5. Monthly profits and costs for Easeamine Products since inception, by distributor and SKU.

6. The projected gross and net unit sales volumes, unit selling process, sales revenue, profit margins, and costs for the Easeamine Products.

7. Ownership and any rights to the Asserted Patents, including by You and any other Person, including the identity of such owners(s), the date(s) when such ownership was obtained, the facts and circumstances concerning such ownership, all Documents Concerning such ownership, any agreements (oral or in writing) relating to such ownership, and any all facts and circumstances relating to any offer(s) to convey any rights and/ownership to any entity or Person (whether performed or not).

8. The manufacture of the Easeamine Products, including the ingredients used, the absolute and relative quantities of the ingredients in the Easeamine Products' formulation, and how and why those ingredients were selected.

9. Your Communications with any Persons other than L'Oréal USA to license and/or enforce any of the Asserted Patents, including any meetings with such Persons, all facts and circumstances Concerning such meetings, the identity of Person(s) involved with such meetings, all Communications relating to such meetings, and all Documents relating to such meetings.

10. Your Communications with L'Oréal USA to license and/or enforce any of the Asserted Patents, including any meetings with L'Oréal USA, all facts and circumstances Concerning such meetings, the identity of Person(s) involved with such meetings, all Communications relating to such meetings, and all Documents relating to such meetings.

11. Licenses, and negotiations related thereto, Concerning the Asserted Patents or the Easeamine Products, including nature, scope, royalty rate, and terms of such licenses, and the identity of all licensees, as well as all entities who were offered and declined a license to the Asserted Patents and the reasons related thereto.

12. Royalties paid by or to You Concerning the Asserted Patents or the Easeamine Products.

13. Your policies relating to licensing any other Person's patents or technology, including patents relating to the Easeamine Products.

14. Your licensing or potential licensing of the Asserted Patents, including the identification of all facts You considered in connection with any decision to license or potentially license the Asserted Patents.

15. Your licensing policies related to the Asserted Patents or the Easeamine Products.

16. Your knowledge of any industry standard royalty rate for the Asserted Patents or the Easeamine Products.

17. The pricing of the Easeamine Products, including pricing strategies, pricing decisions, pricing analyses, pricing negotiations, pricing forecasts, pricing plans, product evaluation analyses, credits and discounts.

18. Your knowledge of the market for the Easeamine Products and any products that are or were, at any time, competitors to the Easeamine Products, including the market share of each and the advertising for each.

19. Any criticism of You and the Easeamine Products, including, but not limited to, the quality of the Easeamine Products.

20. The enforcement, or contemplated enforcement, of the Asserted Patents against other competitors to You or L'Oréal USA.

21. An explanation of all of Your Documents that purport to set forth sales figures, pricing figures, cost information, profit figures, and projections of these figures for the Easeamine Products.

22. Any product or design-around that is an acceptable non-infringing alternative to the inventions recited in any of the asserted claims in the Asserted Patents.

23. The respective contributions of each named inventor to the alleged inventions and other subject matter described and/or claimed in the Patents-in-Suit, and the location and identity of any documents evidencing the same.

24. The dates and circumstances under which the alleged inventions and other subject matter described and/or claimed in the Patents-in-Suit were: (i) first conceived; (ii) first observed experimentally; (iii) first recorded or otherwise described in writing; (iv) first reduced to practice; and (v) the documents that demonstrate all of the above.

25. The disclosures of the alleged inventions and other subject matter described and/or claimed in the Patents-in-Suit, including but not limited to Invention Disclosure No. UMMC97-32, including but not limited to the facts and circumstances Concerning the drafting, preparation, and filing thereof, and any analysis of the prior art related thereto.

26. The facts and circumstances Concerning maintaining the file for Invention Disclosure No. UMMC97-32, including but not limited to: decisions to initiate, continue, or abandon prosecution of the Patents-in-Suit and any Related Patents and Applications; decision to initiate, continue, or abandon licensing efforts related to the alleged inventions and other subject matter described and/or claimed in the Patents-in-Suit and any Related Patents and Applications; and decisions to collect or waive royalties owed by licensees of the same.

27. The research and development efforts, if any, Concerning the alleged inventions and other subject matter described and/or claimed in the Patents-in-Suit, including dates.

28. The data, test results, figures, examples, tables, formulations, compositions, preparations, and processes Concerning the subject matter described and/or claimed in the Patents-in-Suit and any Related Patents and Applications, including but not limited to the data underlying the examples included therein and submitted during prosecution.

29. The research, analysis, study, testing, evaluation, and/or consideration of the amount and/or concentration of topically applied adenosine or any topically applied composition containing adenosine that reaches the "dermal cell layer," including but not limited to the dates, formulations of the tested compositions, methodologies used, and results.

30. The research, analysis, study, testing, evaluation, and/or consideration of the effect of adenosine on cell proliferation, such as dermal cell proliferation, including but not limited to the dates, formulations of the tested compositions, methodologies used, and results.

31. The research, analysis, study, testing, evaluation, and/or consideration of the effect of adenosine on the condition of unbroken skin of a mammal, including wrinkling, roughness, dryness, or laxity of the skin, including but not limited to the dates, formulations of the tested compositions, methodologies used, and results.

32. Clinical studies conducted Concerning the subject matter of the Patents-in-Suit, including but not limited to: (i) the purpose and planning of such clinical studies; (ii) the formulations of the compositions used in such clinical studies; (iii) the protocols of such clinical studies; (iv) conduct of the clinical trials; (v) the results of such clinical studies; (vi) the internal or external publications, reports, or presentations of such clinical studies; (vii) the individuals involved in any such study; (viii) the internal and external communications Concerning any such study (including with physicians, patients, and regulatory agencies); (ix) any documents Concerning any such study; and (x) dates of any such study.

33. The preparation, filing, and prosecution (including appeals or any other issuance or validity proceeding before any national or international patent authority or court) of the applications for the Patents-in-Suit and any Related Patents and Applications, including but not limited to United States Patent App. No. 09/179,006, United States Patent App. No. 09/672,348,

United States Patent App. No. 10/184,810, United States Patent App. No. 10/680,370, United States Patent App. No. 11/473,512, United States Patent App. No. 11/804,904, Canadian Patent App. No. 2,347,979, European Patent App. No. 99 97 0915, Australian Patent App. No. 12310/00, Japanese Patent App. No. 2000-577976, and Korean Patent App. No. 10-2001-7005134, and International Patent App. No. PCT/US99/25020.

34. The affidavits, declarations, and bases for any other factual information submitted to or prepared for submission to a national or international patent authority or court, including but not limited to the United States Patent and Trademark Office, Canadian Intellectual Property Office, European Patent Office, IP Australia, Japan Patent Office, Korean Intellectual Property Office, Patent Court of Korea, or World Intellectual Property Organization, during prosecution of the Patents-in-Suit and any Related Patents and Applications, including experiments and studies underlying statements in the affidavits or declarations.

35. Preparation and submission of the following declarations: (i) "Declaration under 37 C.F.R. § 1.132" by James G. Dobson, Jr., Ph.D. and Michael F. Ethier, Ph.D. dated February 11, 2002 (U.S. Patent App. No. 09/672,348) filed with the United States Patent and Trademark Office; (ii) "Declaration to Support Korean Patent Application No. 2001-7005134" by James G. Dobson, Jr., Ph.D. and Michael F. Ethier, Ph.D. dated October 21, 2004 (Korean Patent App. No. 10-2001-7005134) filed with the Korean Intellectual Property Office; (iii) "Declaration to Support Appeal of Korean Patent Application No. 2001-7005134" by James G. Dobson, Jr., Ph.D. and Michael F. Ethier, Ph.D. dated June 11, 2007 (Korean Patent App. No. 10-2001-7005134) filed with the Patent Court of Korea; and (iv) "Second Declaration to Support Appeal of Korean Patent Application No. 2001-7005134" by James G. Dobson, Jr., Ph.D. and Michael

F. Ethier, Ph.D. dated June 29, 2007 (Korean Patent App. No. 10-2001-7005134) filed with the Patent Court of Korea.

36. The facts and circumstances, and the execution of, all communications between You or anyone on Your behalf and L'Oréal USA, L'Oréal S.A., and/or their alleged agents before this litigation, including but not limited to the allegations that, "[i]n fall of 2003, an agent of [L'Oréal USA and L'Oréal S.A.] contacted Dr. Dobson to discuss the patents-in-suit" (D.I. 13 at ¶¶ 23, 57) and "[i]n March 2015, Brother Dennis Wyrzykowski, President of Teresian Carmelites and Carmel Labs, sent a letter to Jean-Paul Agon, CEO of L'Oréal" (*id*. at ¶ 30)."

37. The factual bases for Plaintiffs' asserted secondary considerations of nonobviousness with respect to the asserted claims of the Patents-in-Suit, and any asserted nexus between such secondary considerations and the asserted claims of the Patents-in-Suit, that allegedly support Your nonobviousness positions for the Patents-in-Suit.

38. All public and third-party disclosures, publications, public uses, sales, and offers for sale of or Concerning the subject matter described and/or claimed in the Patents-in-Suit or any other adenosine skin-care compositions by Plaintiffs or the alleged inventors, if any, before October 26, 1998, including any communications between Plaintiffs or the alleged inventors and any third party Concerning the same.

39. The facts, circumstances, investigators, laboratories, test methodologies and parameters, products and product lots tested, and test results associated with the testing referenced in the correspondence between Plaintiffs and L'Oréal USA or L'Oréal S.A., including but not limited to the March 17, 2015 letter from Dennis W. Wyrzykowski to Jean-Paul Agon, the May 27, 2015 letter from Dennis W. Wyrzykowski to Denis Boulard, the June 24, 2015 letter from Dennis W.

Wyrzykowski to Denis Boulard, the April 1, 2016 e-mail from Matthew A. Ambrose to Michelle O'Brien, and the April 13, 2016 email from Matthew A. Ambrose to Michelle O'Brien.

**CERTIFICATE OF SERVICE**

I hereby certify that on April 8, 2020, a true and correct copy of the foregoing document was caused to be served upon the following counsel of record as indicated:

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*/s/ Katharine L. Mowery*
Katharine L. Mowery (#5629)
mowery@rlf.com

# EXHIBIT 2

**From:** Tamar Lusztig <TLusztig@susmangodfrey.com>
**Sent:** Tuesday, May 26, 2020 7:20 AM
**To:** Kasaraneni, Karthik; Dennis S. Ellis; PH-UMASS v. L'Oreal USDC; Dittmann, Eric W.; Frederick Cottrell; Ashkenazi, Isaac S.; Jason Rawnsley; Jeffrey Moyer; Palys, Joseph E.; Katharine Mowery; Katherine F. Murray; Modi, Naveen; Tymoczko, Nicholas; Serli Polatoglu
**Cc:** Beatrice Franklin; Bill Carmody; Brian Farnan; Davida Brook; Justin A. Nelson; Keeley Lombardo; Lucas I. Silva; Matthew Lowrie; Michael J. Farnan ; Rodney Polanco
**Subject:** RE: UMass v. L'Oreal: Depositions

Karthik,

We have a slight modification to make to the 30(b)(6) designations for next week.

Subject to our written objections and our subsequent email exchange regarding scope, the following witnesses will testify about the following topics:

Dr. McNamara: 7, 9, 11, 12, 13, 14, 15, 16, 20, 22, 26, 30, 33, 36, 37
Dr. Dobson: 8, 23, 24, 25, 27, 28, 29, 30, 31, 32, 34, 35, 36, 38
Mr. Wyrzykowski: 2, 10, 12, 13, 14, 15, 36
Mr. Menard: 1, 3, 4, 5, 6, 17, 18, 19, 20, 21, 22, 37

Thanks.

-Tamar

---

**From:** Tamar Lusztig
**Sent:** Monday, May 18, 2020 7:26 PM
**To:** Kasaraneni, Karthik <karthikkasaraneni@paulhastings.com>; Dennis Ellis <dellis@bgrfirm.com>; PH-UMASS v. L'Oreal USDC <PH-UMass-LOreal-USDC@paulhastings.com>; Dittmann, Eric W. <ericdittmann@paulhastings.com>; Frederick Cottrell <cottrell@rlf.com>; Ashkenazi, Isaac S. <isaacashkenazi@paulhastings.com>; Jason Rawnsley <rawnsley@rlf.com>; Jeffrey Moyer <moyer@rlf.com>; Palys, Joseph E. <josephpalys@paulhastings.com>; Katharine Mowery <mowery@rlf.com>; Katherine Murray <kmurray@bgrfirm.com>; Modi, Naveen <naveenmodi@paulhastings.com>; Tymoczko, Nicholas <nicholastymoczko@paulhastings.com>; Serli Polatoglu <spolatoglu@bgrfirm.com>
**Cc:** Beatrice Franklin <BFranklin@susmangodfrey.com>; Bill Carmody <bcarmody@SusmanGodfrey.com>; Brian Farnan <bfarnan@farnanlaw.com>; Davida Brook <DBrook@susmangodfrey.com>; Justin A. Nelson <jnelson@SusmanGodfrey.com>; Keeley Lombardo <klombardo@susmangodfrey.com>; Lucas I. Silva <lsilva@foley.com>; Matthew Lowrie <mlowrie@foley.com>; Michael J. Farnan <mfarnan@farnanlaw.com>; Rodney Polanco <RPolanco@susmangodfrey.com>
**Subject:** RE: UMass v. L'Oreal: Depositions

Karthik,

Dr. Michael Ethier will be available for his deposition on 6/2.

Subject to our written objections and our subsequent email exchange regarding scope, the following witnesses will testify about the following topics:

Dr. McNamara: 7, 9, 11, 12, 13, 14, 15, 16, 20, 22, 26, 30, 33, 36, 37
Dr. Dobson: 8, 23, 24, 25, 27, 28, 29, 30, 31, 32, 34, 35, 36, 38
Mr. Wyrzykowski: 1, 2, 3, 4, 5, 6, 10, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 36, 37

Could you please let us know by close of business tomorrow whether you intend to proceed with the Steinman, Warshawsky, or Decker depositions so that we can get them scheduled, or not, as the case may be? And similarly, can you please let us know by close of business tomorrow whether you plan to use a half day or less for any of the witnesses we will be presenting for deposition?

Thanks!

-Tamar

---

**From:** Kasaraneni, Karthik <karthikkasaraneni@paulhastings.com>
**Sent:** Monday, May 18, 2020 6:14 PM
**To:** Tamar Lusztig <TLusztig@susmangodfrey.com>; Dennis Ellis <dellis@bgrfirm.com>; PH-UMASS v. L'Oreal USDC <PH-UMass-LOreal-USDC@paulhastings.com>; Dittmann, Eric W. <ericdittmann@paulhastings.com>; Frederick Cottrell <cottrell@rlf.com>; Ashkenazi, Isaac S. <isaacashkenazi@paulhastings.com>; Jason Rawnsley <rawnsley@rlf.com>; Jeffrey Moyer <moyer@rlf.com>; Palys, Joseph E. <josephpalys@paulhastings.com>; Katharine Mowery <mowery@rlf.com>; Katherine Murray <kmurray@bgrfirm.com>; Modi, Naveen <naveenmodi@paulhastings.com>; Tymoczko, Nicholas <nicholastymoczko@paulhastings.com>; Serli Polatoglu <spolatoglu@bgrfirm.com>
**Cc:** Beatrice Franklin <BFranklin@susmangodfrey.com>; Bill Carmody <bcarmody@SusmanGodfrey.com>; Brian Farnan <bfarnan@farnanlaw.com>; Davida Brook <DBrook@susmangodfrey.com>; Justin A. Nelson <jnelson@SusmanGodfrey.com>; Keeley Lombardo <KLombardo@susmangodfrey.com>; Lucas I. Silva <lsilva@foley.com>; Matthew Lowrie <mlowrie@foley.com>; Michael J. Farnan <mfarnan@farnanlaw.com>; Rodney Polanco <RPolanco@susmangodfrey.com>
**Subject:** RE: UMass v. L'Oreal: Depositions

Tamar,

Thank you for providing these dates. We are checking to see if they work for us. Please let us know which of these witnesses, if any, you will be designating as 30(b)(6) witnesses, and for which topics. Please also provide proposed deposition dates for the remaining witnesses.

Thank you,
Karthik

---

**From:** Tamar Lusztig <TLusztig@susmangodfrey.com>
**Sent:** Saturday, May 16, 2020 9:37 PM
**To:** Dennis Ellis <dellis@bgrfirm.com>; PH-UMASS v. L'Oreal USDC <PH-UMass-LOreal-USDC@paulhastings.com>; Dittmann, Eric W. <ericdittmann@paulhastings.com>; Frederick Cottrell <cottrell@rlf.com>; Ashkenazi, Isaac S. <isaacashkenazi@paulhastings.com>; Jason Rawnsley <rawnsley@rlf.com>; Jeffrey Moyer <moyer@rlf.com>; Palys, Joseph E. <josephpalys@paulhastings.com>; Katharine Mowery <mowery@rlf.com>; Katherine Murray <kmurray@bgrfirm.com>; Modi, Naveen <naveenmodi@paulhastings.com>; Tymoczko, Nicholas <nicholastymoczko@paulhastings.com>; Serli Polatoglu <spolatoglu@bgrfirm.com>
**Cc:** Beatrice Franklin <BFranklin@susmangodfrey.com>; Bill Carmody <bcarmody@SusmanGodfrey.com>; Brian Farnan <bfarnan@farnanlaw.com>; Davida Brook <DBrook@susmangodfrey.com>; Justin A. Nelson <jnelson@SusmanGodfrey.com>; Keeley Lombardo <KLombardo@susmangodfrey.com>; Lucas I. Silva <lsilva@foley.com>; Matthew Lowrie <mlowrie@foley.com>; Michael J. Farnan <mfarnan@farnanlaw.com>; Rodney

Polanco <RPolanco@susmangodfrey.com>; Tamar Lusztig <TLusztig@susmangodfrey.com>
**Subject:** [EXT] UMass v. L'Oreal: Depositions

Counsel,

We are still confirming a few dates, but did not want to delay in getting you the below information. The following witnesses will be available for remote video depositions on the following dates:

Dr. Jim McNamara: 5/27
Dr. James Dobson: 5/27
Dr. Satinder Rawat: 5/29
Dr. Kevin Lehman: 6/1
Renato Jose: 6/1
Frank Gallagher: 6/2
Paul Menard: 6/4
Dennis Wyrzykowski 6/5

For now, the depositions will begin at 10 AM in the deponent's home time zone; though we reiterate our earlier request to let us know if any of the depositions will be going less than half a day in which case we may adjust.

-Tamar

Tamar Lusztig | Susman Godfrey LLP
1301 Avenue of the Americas, 32nd Floor | New York, NY 10019
212-729-2007 (direct) | 617-967-8748 (cell)

# EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | |
|---|---|
| UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>L'ORÉAL USA, INC.,<br><br>Defendant. | C.A. No. 17-cv-868-CFC-SRF |

**DECLARATION OF DR. RYAN CHEU**

I, Dr. Ryan Cheu, declare as follows:

1. I am an Associate Director of Bioanalytical Chemistry at Emery Pharma. I hereby submit this declaration in support of University of Massachusetts and Carmel Laboratories, LLC's ("Plaintiffs") Motion to Strike and Motions for Partial Summary Judgment of No Anticipation and Non-Obviousness.

2. Emery Pharma was first contacted by Plaintiffs' counsel, Susman Godfrey, on July 7, 2020.

3. Emery Pharma was engaged by Susman Godfrey on July 9, 2020, to make and test certain formulations corresponding to Table 3 of JP153 and Example 5 of DE107.

4. Emery Pharma placed an order for the materials necessary to make and test

the first set of formulations on July 14, 2020.

5. Emery Pharma received the materials necessary to make and test the first set of formulations on July 27, 2020.

6. Between July 27, 2020, and October 15, 2020, Emery Pharma continuously tested 20 formulations.

7. Making and testing the first formulations took approximately four weeks. Making and testing additional formulations took approximately one week each.

8. Additional ingredients had to be ordered, which further extended the timeline for making and testing formulations. Some ingredients, such as Poly(acrylamide-co-acrylic acid) and Poly(methyl vinyl ether-*alt*-maleic acid), take up to 5 days to arrive after an order is placed.

9. Emery Pharma decided what formulations to make and test in part because we chose ingredients that the lab already had or would be quick to order.

10. If we had more time to order materials, make the formulations, and conduct our testing, we would have tested additional and different formulations.

11. Based on the testing conducted to date, if given sufficient time, I believe it would be possible to develop formulations corresponding to any embodiment of the prior art references, using ingredients and manufacturing methods commonly known in the 1997-1998 time period, each of which would not cause adenosine to be applied to the dermal cells in the claimed ranges of the patents-in-suit.

12. A summary of my opinions regarding the formulations Emery Pharma made and tested is attached as **Exhibit A**. I am prepared to submit a supplemental report in accordance with Federal Rule of Civil Procedure 26, should the Court allow.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: October 16, 2020

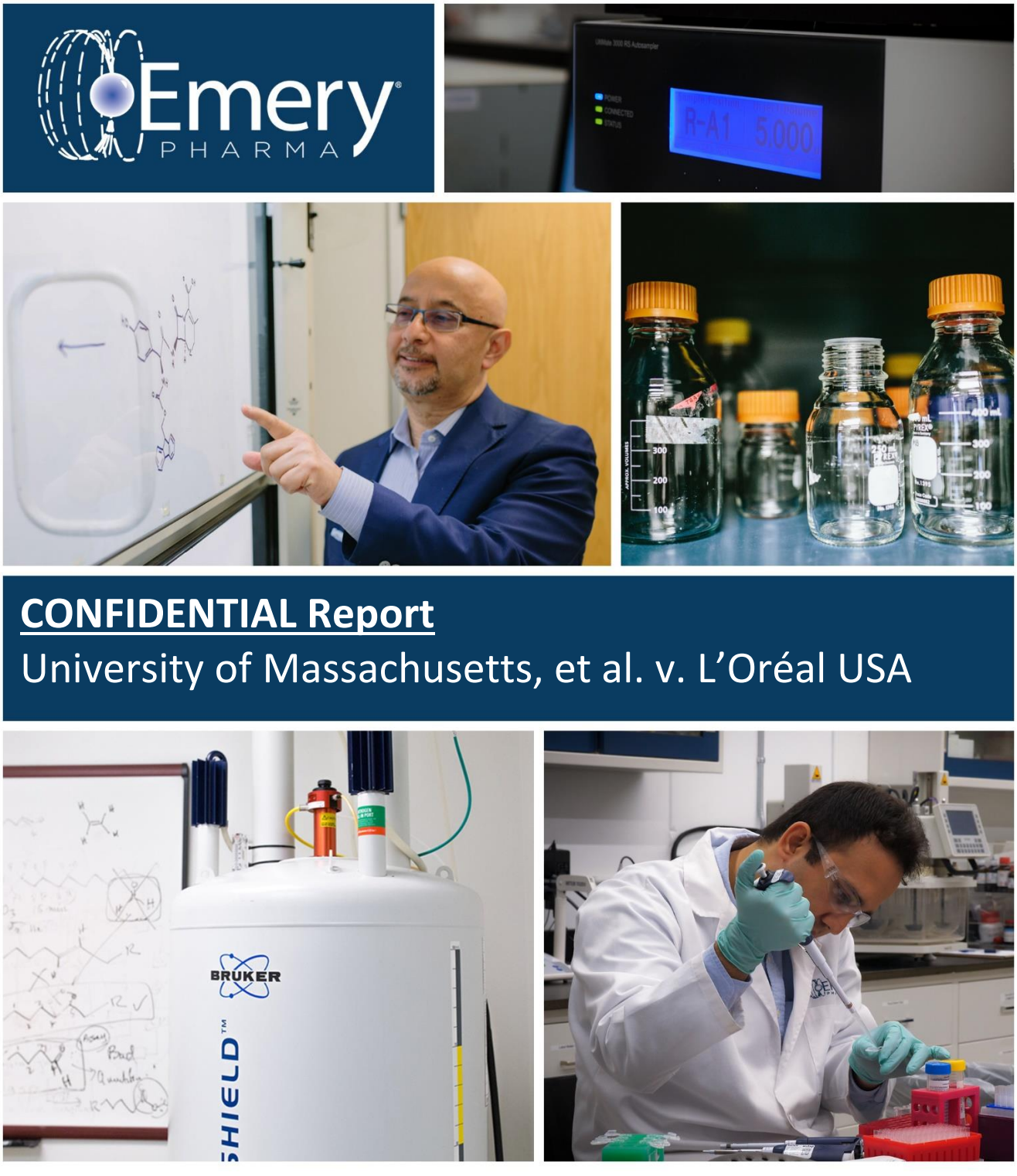
/s/

Ryan Cheu

# EXHIBIT A

# CONFIDENTIAL REPORT

REPORT #: RSGF-NB200709



# CONFIDENTIAL REPORT

REPORT #: RSGF-NB200709

October 16, 2020

**PREPARED BY:**

*Signature* *Date*

October 16, 2020

## INTRODUCTION

1. Susman Godfrey LLP, counsel for Plaintiffs University of Massachusetts and Carmel Labs ("Counsel") contracted Emery Pharma for formulation development and potential in vitro Drug Release Testing (IVRT). In order to determine the permeability of the test articles (developed at Emery Pharma), we utilized a Franz diffusion cell apparatus to study IVRT for the developed test articles.
2. The purpose of these experiments was to determine the dermal delivery of adenosine from two topical prior art formulations. Counsel had asked us to formulate and test the JP153 (Table 3, Lane Report) and DE107 (Example 5, Lane Report) creams for dermal adenosine delivery levels using Franz Diffusion Cells and in vitro release testing in accordance with the testing parameters used by Tioga Research.

## MATERIALS AND METHOD

3. Following the constituent list for the creams provided by Counsel, Emery Pharma formulated the JP153 cream as follows. Stearic acid (1% wt.), cetanol (0.50% wt.), glycerol monostearate (0.50% wt.), squalene (20% wt.), and Sorbitan monooleate (2% wt.) were mixed and heated to 75°C for 1 hour at 1400RPM. Poly (ethylene oxide) Sorbitan monostearate (2% wt.), sodium hydroxide (0.05% wt.), methylparaben (0.10% wt.), water (73.35% wt.), and a carboxyvinyl polymer (0.10% wt.) was then added and mixed at 1400RPM for 2 hours at 75°C.[1]
4. Emery Pharma tested a series of carboxyvinyl polymers including: polyacrylic acid, poly(2-ethylacrcylic acid), poly(methyl vinyl ether-*alt*-maleic acid), and poly(acrylamide-co-acrylic acid). These carboxyvinyl polymers would have been commonly known and used in the 1997-1998 time period.[2] Following the 2-hour mixing, the cream was slowly cooled to 30 °C with constant stirring at 1400 RPM. The cooling process took ~1 hour and then left at 30 °C for an additional

[1] The mixing, heating, and cooling for each formulation, where not specified by JP153 or DE107, were conducted according to established methods available in the 1997-1998 time period. *See, e.g.*, Eccleston GM. *Functions of mixed emulsifiers and emulsifying waxes in dermatological lotions and creams*. Colloids and Surfaces A: Physicochemical and Engineering Aspects. 1997 May 15;123:169-82.

[2] *See, e.g.* Perrin P, et al. *Emulsions stabilized with hydrophobically modified poly (acrylic acid)*. In Trends in Colloid and Interface Science XI 1997 (pp. 228-238); Nagashima S, et al. *Preparation of monodisperse poly (acrylamide-co-acrylic acid) hydrogel microspheres by a membrane emulsification technique and their size-dependent surface properties*. Colloids and Surfaces B: Biointerfaces. 1998 Jun 15;11(1-2):47-56.

hour. Either adenosine (0.2% wt.) or hamamelitannin (0.1% wt.) + adenosine (0.1% wt.), and fragrance (0.20% wt.)[3] was then added and the entire cream was mixed and heated to 40 °C where it was maintained for 30 minutes. Emery Pharma tested both rose water and lavender water for all carboxyvinyl polymers used. These fragrances would have been commonly known and used in the 1997-1998 time period.[4] Emery Pharma then added adenosine $^{13}C_5$ (0.1% wt.) in accordance with the formulation screening campaign conducted by Tioga Research.

5. Following the constituent list for the creams provided by Counsel, Emery Pharma formulated the DE107 cream as follows. Glyceryl stearate (3% wt.), behenyl alcohol (5% wt.), isopropyl palmitate (3% wt.), octyl dodecanol (3% wt.), and glycerin (5% wt.) was added and mixed at 1400 RPM for 1 hour at 75 °C. Water (74.4% wt.) was added and the cream was slowly cooled to 30 °C with constant stirring at 1400 RPM for 2 hours. Adenosine (0.1% wt.), fragrance (0.2% wt.), and preservative (6.3% wt.) were added and the entire cream was mixed and heated to 40 °C for 1 hour. Following this, Emery Pharma then added adenosine-$^{13}C_5$ (0.1% wt.) in accordance with the formulation screening campaign conducted by Tioga Research. For the DE107 cream, Emery Pharma tested a series of preservatives including sodium citrate, sodium benzoate, caprylyl glycol, sodium chloride, and honey. These preservatives would have been commonly known and used in the 1997-1998 time period.[5] Emery Pharma also tested two different fragrances: rose water and lavender water.
6. To determine the flux of adenosine into and through the skin, Emery Pharma developed an analytical method to detect adenosine-$^{13}C_5$ (Toronto Research Chemicals: A280402) using liquid chromatography mass spectrometry (LC/MS). Stock solution and calibration standards were prepared by weighing 5 mg of adenosine-$^{13}C_5$ and dissolved in 5 mL of 50%/50% water/methanol. Calibration standards were diluted using 50%/50% water/methanol ranging from 10-0.001 µg/mL. Table 1 details the LC/MS parameters.
7. Human excised skin was purchased from BIOIVT and dermatomed to 250 µm thickness leaving only the stratum corneum, epidermis, and dermis intact. The skin tissue was obtained from a female donor, age 53. This skin was shipped to Emery Pharma on dry ice and stored at -20 °C until use. Prior to use, the skin pieces were removed from the freezer and allowed to thaw at room temperature for 25 minutes. The skin was then submerged into 200 mL of distilled water and allowed to rest for 5 minutes at room temperature. The skin was then washed and rinsed two times. The skin was then cut to fit on the Franz diffusion cells.

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[3] Corresponding to Example 1 and Comparative Example 1 from JP153, Tables 3-5.

[4] *See, e.g.*, Rastogi SC, et al. *Natural ingredients based cosmetics: Content of selected fragrance sensitizers*. Contact Dermatitis. 1996 Jun;34(6):423-6; Brud, WS. *FORMULATION AND EVALUATION OF FRAGRANCE FOR PERFUMERY COSMETICS AND RELATED PRODUCTS*. In A Manual on the Essential Oil Industry, K. TULEY DE SILVA, ed. 1995 Nov:179; Scheinman PL. *Allergic contact dermatitis to fragrance: a review*. American Journal of Contact Dermatitis. 1996 Jun 1;7(2):65-76.

[5] *See, e.g.*, Crane E. *The past and present importance of bee products to man*. InBee Products 1997 (pp. 1-13); Jeddar A, et al. *The antibacterial action of honey. An in vitro study*. Suid-Afrikaanse tydskrif vir geneeskunde. 1985 Feb;67(7):257-8; Liyanage D, Mawatha B. *Health benefits and traditional uses of honey: A review*. J. Apith. 2017; Zumla, A. and Lulat, A. *Honey-a remedy rediscovered*. Journal of the Royal Society of Medicine, Vol. 82 (July 1989), 384-385; Chipley JR. *Sodium benzoate and benzoic acid*. Antimicrobials in foods. 1993;2:11-48.

8. The Franz diffusion cells had a receptor volume of 5 mL and an exposure area of 0.64 $cm^2$. The receptor fluid used was 0.01% Sodium Azide pH 5.5 (using 0.1 N HCl). The receptor fluid was added to each Franz cell with a Teflon coated magnetic stir bar. The excised skin was added and the donor and receptor well compartments were aligned and clamped. Each section of skin was visually assessed for integrity issues.
9. Following the donor and receptor well compartment alignment, the Franz Cell apparatus was equilibrated for 20 minutes at 32 °C. Any air bubbles that formed were removed by tilting the cells until the bubble was eliminated. The cells were continuously stirred throughout the equilibration and experiment. After 20 minutes, the skin was re-assessed for signs of sweating or wetness. If present, the skin was removed, and a new excised skin was added to the Franz Cell.
10. Each Franz cell was dosed with 5 µL of formulations using a positive pipet. Once the dose was applied, it was spread evenly across the exposed skin using a glass rod. Following the last timepoint, 24 hours, a 300 µL aliquot was abstracted from the sampling port of each Franz Cell. Aliquots were stored at 4 °C prior to LC/MS analysis. Samples were analyzed within 2 days of collection.
11. After 24 hours, a 200 µL aliquot of 50%/50% water/methanol was added to the donor compartment and allowed to sit for 5 minutes. The aliquot was then removed, and the skin was tapped dry with a clean KimWipe. The skin was then subjected to tape stripping using cellophane tape three times. The tape was applied lightly to remove the upper most layers of the stratum corneum. After tape stripping, the remaining skin was placed briefly on a hot plate at 60 °C for 10 seconds to ease the separation. The skin was then separated into the epidermal and dermal layer using spatulas. The epidermal and dermal layers were then separately placed in glass vials containing 0.5mL of 50%/50% water/methanol and incubated at 40 °C for 24 hours with gentle agitation. After 24 hours, the samples were collected and stored at 4 °C prior to LC/MS analysis.
12. The LC/MS peak areas were converted to ug/mL using the standard curve described in "Analytical Methods". The concentrations were multiplied by either 5mL for receptor volume (transdermal) or 0.5 mL skin extraction volume (epidermal/dermal). This value was then divided by the molecular weight of adenosine. For the dermis, the value was then divided by 80 µL to account for the volume of the dermis. This value was generated by the average weight of the dermal layer and assuming specific gravity is 1.00 for skin. Thus 80 mg = 80 µL. For the epidermal layer, this value was 40 µL. To account for the 0.2% adenosine in the JP153 cream that was tested, the value was also divided by ratio of adenosine-$^{13}C_5$ /adenosine.

**RESULTS AND DISCUSSION**

13. The summary of the DE107 cream data is presented in Figure 1 and 2 for the dermal and epidermal delivery, respectively. The transdermal delivery was below our limit of detection (BLOD) and the data is not shown. Table 2 summarizes the adenosine delivery and standard error calculations. The summary of JP153 cream data is presented in Figure 3 and 4 for the dermal and epidermal delivery, respectively. The transdermal delivery was BLOD and the data is

not shown. Table 3 summarizes the adenosine delivery and standard error calculations for the JP153 cream testing.

14. The JP153 formulation using Poly(acrylamide-co-acrylic acid) and either fragrance demonstrated the lowest adenosine penetration in both the dermis and epidermis. This was consistent for both rounds of testing, including testing comparative example 1, adenosine 0.2%. All the formulations demonstrated below limit of detection (LOD) transdermal delivery. Based on our LC/MS method detection limit this is equivalent to a less than $2.3x10^{-8}$ M delivery.
15. The DE107 formulations using honey and either fragrance demonstrated the lowest adenosine penetration, below our limit of detection for adenosine penetration in the dermis, epidermis, and transdermal. Based on our LC/MS method detection limit this is equivalent to a less than $2.3x10^{-8}$ M delivery.

**CONCLUSION**

16. The JP153 formulation using Poly(acrylamide-co-acrylic acid) and either fragrance, and the DE107 formulations using honey and either fragrance, resulted in application of adenosine to the dermal cells at a concentration below $10^{-7}$ M.

**Tables and Figures**

**Table 1: LC/MS Parameters**

| | |
|---|---|
| Instrument | Agilent 1200 Series HPLC and 6410 Triple Quad LC/MS |
| Column | Eclipse XDB-C18 150 x 4.6mm, 5um |
| Column Temp | 40°C |
| MS Detection (adenosine) | ESI : Positive mode M/Z 268 |
| MS Detection (adenosine-$^{13}C_5$) | ESI : Positive mode M/Z 273 |
| Mobile Phase A | 0.1% Formic Acid in Water |
| Mobile Phase B | Methanol |
| Flow Rate | 0.2mL/min |
| Isocratic | 0-5 minutes: 10%B |
| Injection volume (uL) | 10 |

# CONFIDENTIAL REPORT

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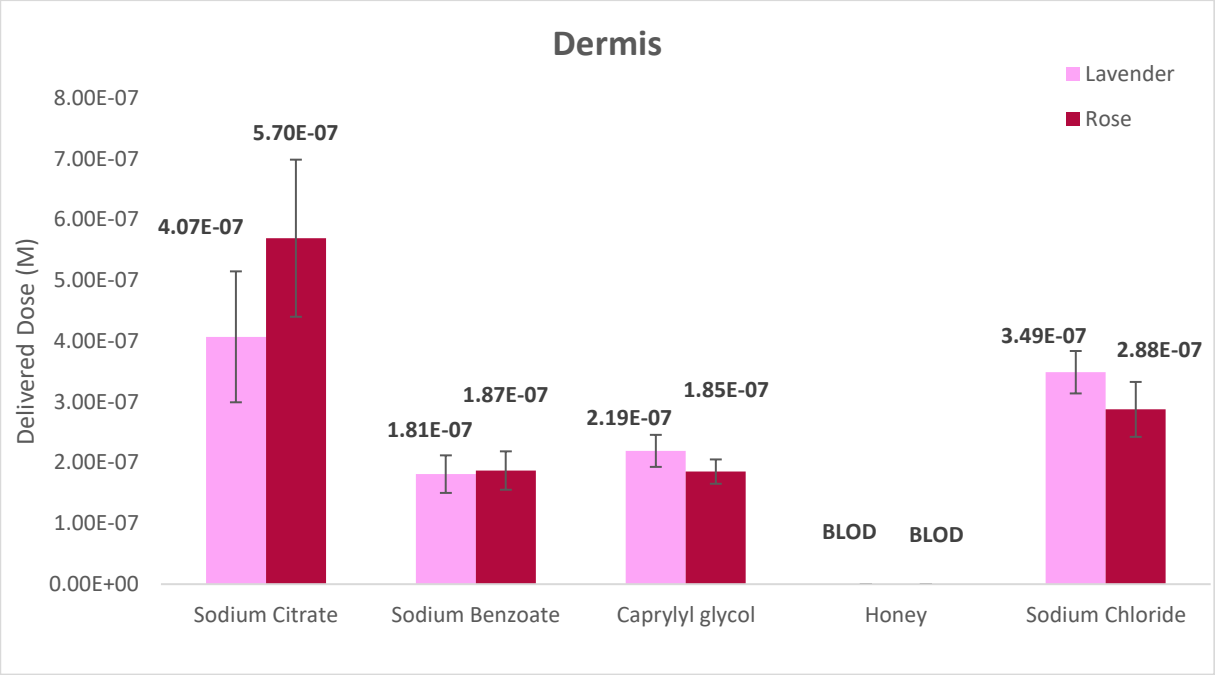


**Figure 1: DE107 Summarized Dermal Delivery of Adenosine. n=6. Error bars represent standard error.**

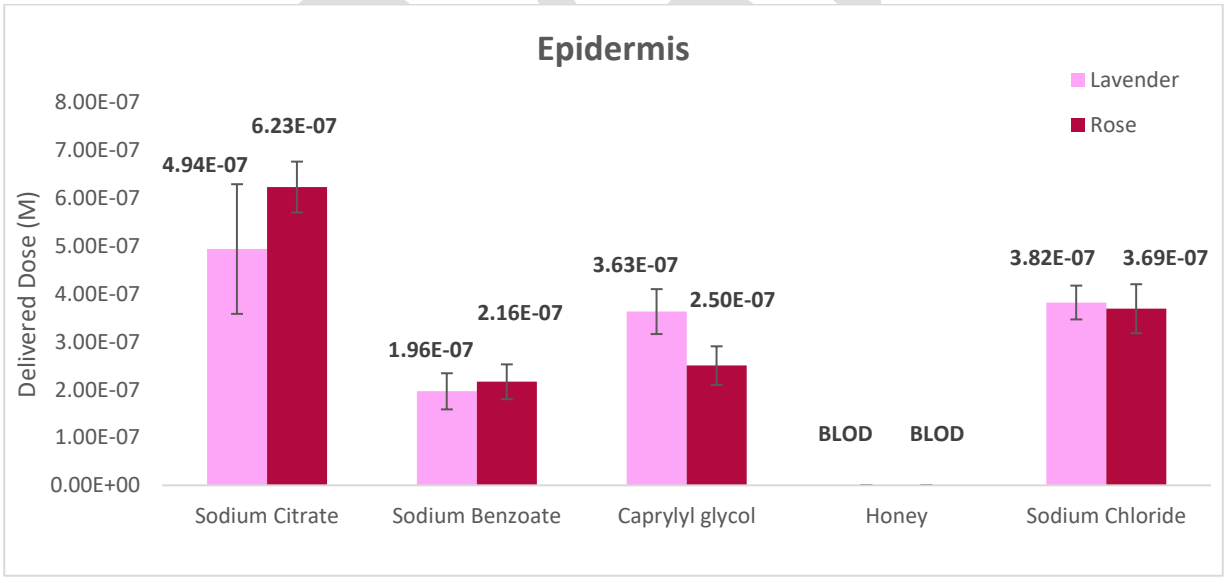


**Figure 2: DE107 Summarized Epidermal Delivery of Adenosine. n=6. Error bars represent standard error.**

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# CONFIDENTIAL REPORT

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**Table 2: DE107 Summarized Average Delivery of Adenosine. n=6**

| Preservative | Fragrance | Transdermal (M) | Epidermis (M) | *STD Error* | Dermis | *STD Error* |
|---|---|---|---|---|---|---|
| Sodium Citrate | Lavender | BLOD | 4.94E-07 | 1.35E-07 | 4.07E-07 | 1.08E-07 |
| Sodium Citrate | Rose | BLOD | 6.23E-07 | 5.31E-08 | 5.70E-07 | 1.29E-07 |
| Sodium Benzoate | Lavender | BLOD | 1.96E-07 | 3.78E-08 | 1.81E-07 | 3.09E-08 |
| Sodium Benzoate | Rose | BLOD | 2.16E-07 | 3.64E-08 | 1.87E-07 | 3.16E-08 |
| Caprylyl glycol | Lavender | BLOD | 3.63E-07 | 4.70E-08 | 2.19E-07 | 2.63E-08 |
| Caprylyl glycol | Rose | BLOD | 2.50E-07 | 4.03E-08 | 1.85E-07 | 2.00E-08 |
| Honey | Lavender | BLOD | BLOD | BLOD | BLOD | BLOD |
| Honey | Rose | BLOD | BLOD | BLOD | BLOD | BLOD |
| Sodium Chloride | Lavender | BLOD | 3.82E-07 | 3.53E-08 | 3.49E-07 | 3.49E-08 |
| Sodium Chloride | Rose | BLOD | 3.69E-07 | 5.12E-08 | 2.88E-07 | 4.52E-08 |

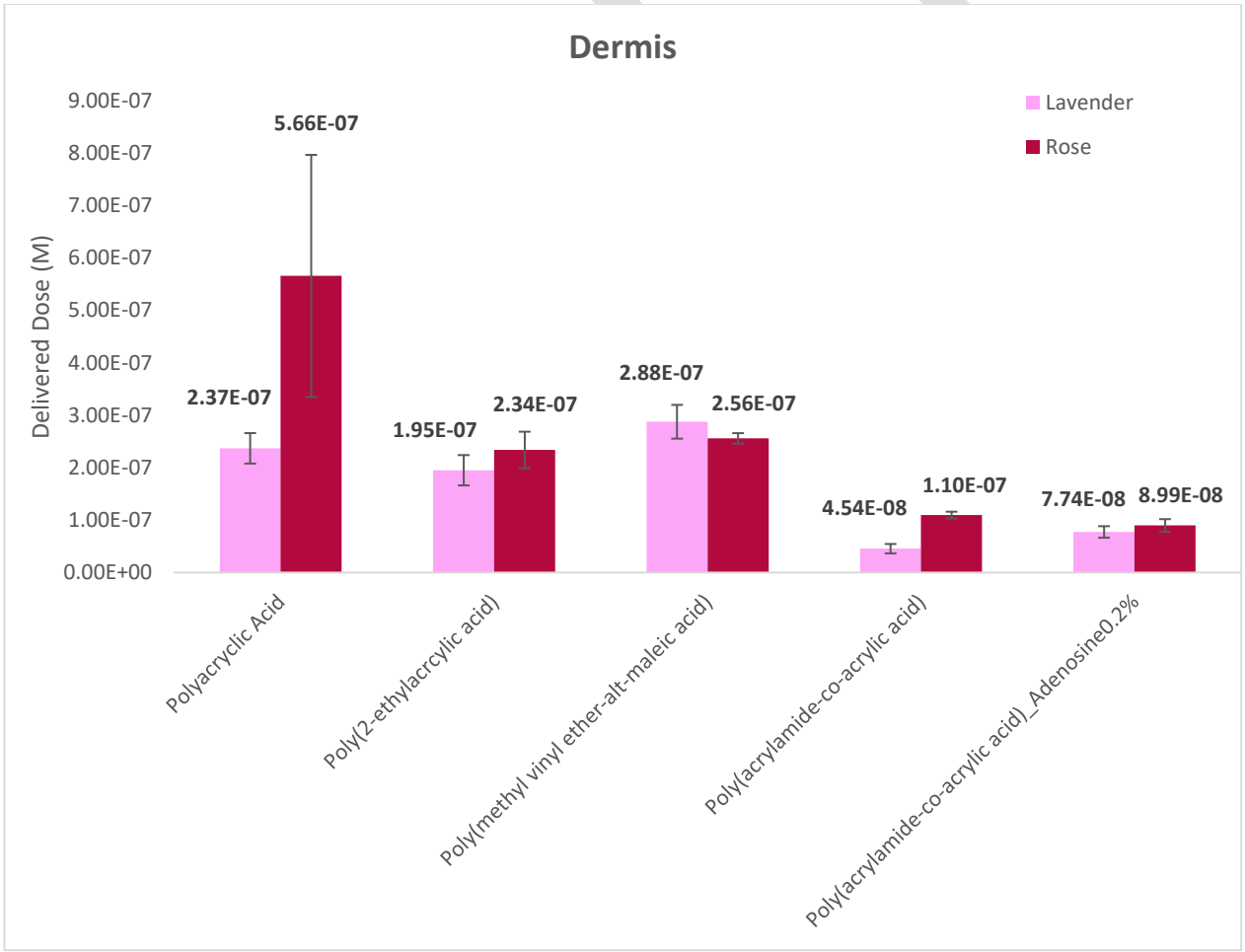


**Figure 3: JP153 Summarized Dermal Delivery of Adenosine. n=6. Error bars represent standard error.**

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# CONFIDENTIAL REPORT

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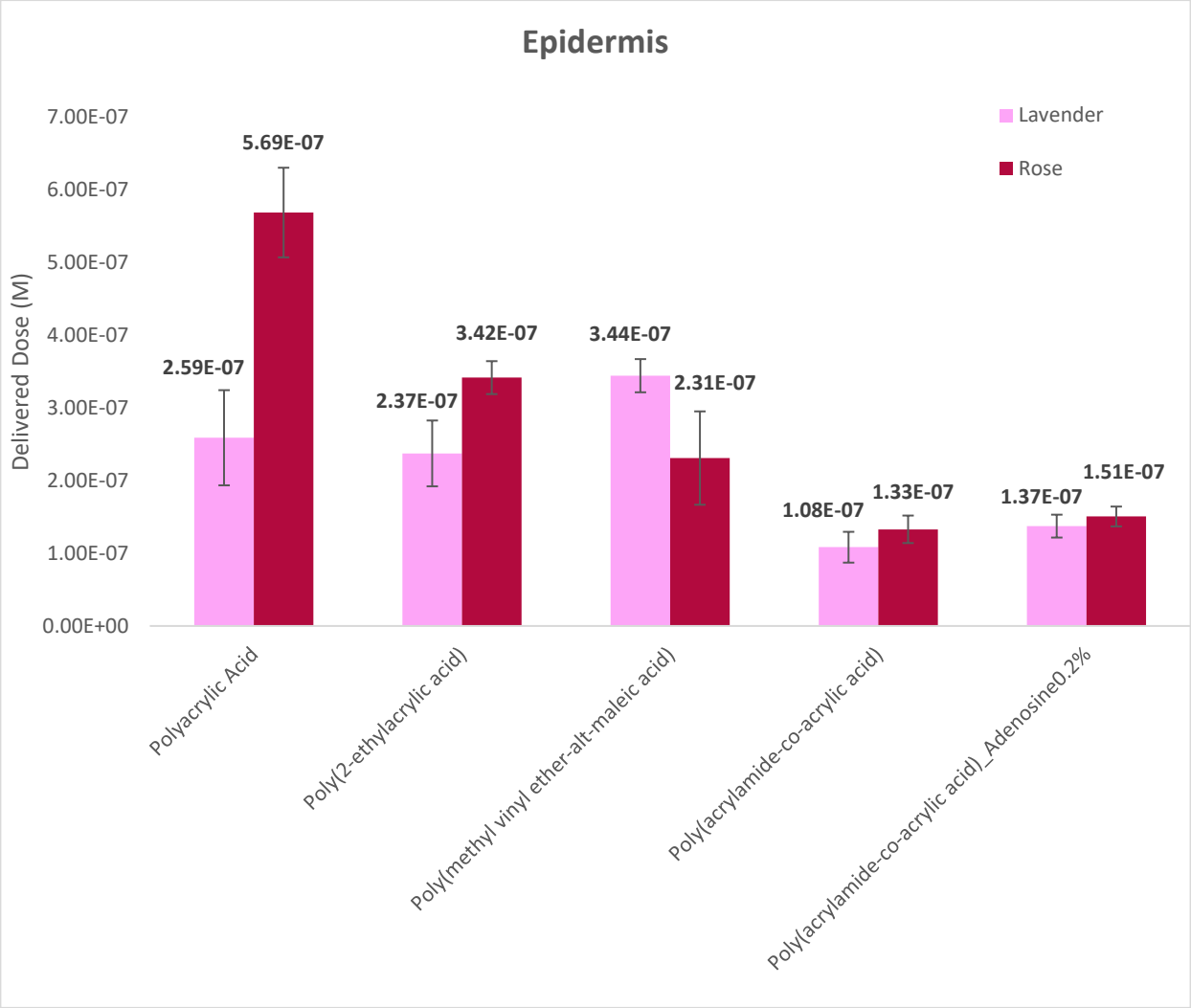


**Figure 4: JP153 Summarized Epidermal Delivery of Adenosine. n=6. Error bars represent standard error.**

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**Table 3: JP153 Summarized Average Delivery of Adenosine. n=6.**

| Carboxyvinyl Polymer | Fragrance | Transdermal (M) | Epidermis (M) | *STD Error* | Dermis (M) | *STD Error* |
|---|---|---|---|---|---|---|
| **Polyacrylic Acid** | Lavender | 0 | 2.59E-07 | 6.54E-08 | 2.37E-07 | 2.90E-08 |
| | Rose | 0 | 5.69E-07 | 6.16E-08 | 5.66E-07 | 2.31E-07 |
| **Poly(2-ethylacrcylic acid)** | Lavender | 0 | 2.37E-07 | 4.53E-08 | 1.95E-07 | 2.89E-08 |
| | Rose | 0 | 3.42E-07 | 2.27E-08 | 2.34E-07 | 3.49E-08 |
| **Poly(methyl vinyl ether-*alt*-maleic acid)** | Lavender | 0 | 3.44E-07 | 2.28E-08 | 2.88E-07 | 3.22E-08 |
| | Rose | 0 | 2.31E-07 | 6.42E-08 | 2.56E-07 | 9.96E-09 |
| **Poly(acrylamide-co-acrylic acid)** | Lavender | 0 | 1.08E-07 | 2.12E-08 | 4.54E-08 | 8.95E-09 |
| | Rose | 0 | 1.33E-07 | 1.89E-08 | 1.10E-07 | 6.47E-09 |
| **Poly(acrylamide-co-acrylic acid)_Adenosine0.2%** | Lavender | 0 | 1.37E-07 | 1.57E-08 | 7.74E-08 | 1.10E-08 |
| | Rose | 0 | 1.51E-07 | 1.36E-08 | 8.99E-08 | 1.19E-08 |

# EXHIBIT 4

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | |
|---|---|
| UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>L'ORÉAL USA, INC.,<br><br>Defendant. | C.A. No. 17-cv-868-CFC-SRF |

**DECLARATION OF DR. BOZENA MICHNIAK-KOHN**

I, Dr. Bozena Michniak-Kohn, declare as follows:

1. I am a full tenured Professor of Pharmaceutics at the Ernest Mario School of Pharmacy at Rutgers, the State University of New Jersey, Piscataway NJ (Busch campus). I have been retained by the University of Massachusetts and Carmel Laboratories, LLC ("Plaintiffs") as a technical expert witness with respect to the proceedings currently before the Court in the above-captioned matter. I hereby submit this declaration in support of Plaintiffs' Motion for Summary Judgment of No Anticipation.

2. I submitted a rebuttal expert report on July 21, 2020, where I opined, among other things, that DE107 and JP153 do not inherently anticipate the patents-in-suit.

3. I have reviewed the summary of testing conducted by Emery Pharma and the

Declaration of Dr. Ryan Cheu.

4. Dr. Cheu's testing further confirms my opinions that DE107 and JP153 do not inherently anticipate the patents-in-suit because the testing shows that the DE107 and JP153 embodiments Dr. Lane tested do not necessarily cause adenosine to be applied to the dermal cells within the claimed concentrations of the patents-in-suit.

5. I am prepared to submit a supplemental expert report addressing Dr. Cheu's testing, should the Court allow.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: October 16, 2020

/s/ Bozena Michniak-Kohn

**CERTIFICATION OF COMPLIANCE**

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 674 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)

Dated: October 16, 2020